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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,215	03/24/2004	Christopher Jude Amies	2002P12618US01	3926

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EXAMINER	
LAMPRECHT, JOEL	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
08/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,215	AMIES ET AL.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8-13 and 16-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8-13 and 16-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 6, 8-13, 16-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Kapatoes et al (6,661,870) in view of Suddarth et al (US 7,011,814 B2). Kapatoes et al disclose the use of both CT and MRI images in the treatment of an area of interest within a patient and the design of therapy plans before, during, and after rounds of radiation therapy are delivered to the patient (Col 2 Line 18-Col 4 Line 30). Specifically they disclose taking a scout image of the area of interest (Col 5 Line 40-57), creating a plan (Col 5 Line 45-62), validating the initial image once a patient is ready for therapy (Col 5 Line 58-Col 6 Line 30), modifying the treatment plan to account for

anatomical and positional changes at this point (Col 6 Line 5-50), delivering a dose of therapy and monitoring the dosage and therapy received during the treatment (Col 7 Line 20-50), updating the plan and performing additional treatment as needed based on anatomical and physiological changes of the diseased state of the patient (Col 7 Line 1-30, Col 3 Line 5-45), including the level of radiation received and therefore the stage of treatment at both the tumor site and the surrounding tissues (Col 6 Line 30-50). These physiological and clinical measurements are performed by imaging in an MRI/CT lab and the updating of the plan can include modifications between dosing due to unexpected changes in the tumor site thereby inducing an unscheduled break into the therapy session (Col 2 Line 40-47, Col 3 Line 58-Col 4 Line 17). Updated plans are automatically prescribed and are updated further or verified by the operator or treatment planner (Col 3 Line 5-35, Col 3 Line 58-Col 4 Line 17). The plans include dosage levels, target sites, physiological locations and identifications of tissues of interest which are all capable of being updated before, between, or for future therapy sessions (Col 5 Line 34-Col 7 Line 29, Col 6 Line 30-50, Col 3 Line 5-Col 4 Line 30)

Kapatoes et al disclose what is listed above, and also disclose methods for adjusting the prescription of radiation to a tumor or target site, but do not disclose monitoring external factors including stage of disease or treatment, and updating the prescription based on those factors. Attention is directed to the secondary reference to Suddarth et al which discloses a system and method for monitoring physiological factors to indicate the stage of the therapy and physiological state of the patient via metabolic, antibody, bio-response and kinetic measurements of a patient for the updating of

treatment protocols (Col 6 Line 20-Col 7 Line 47). These methods and systems of updating therapy prescriptions allow for an updated protocol or treatment based on the biological factors measured. It would have been obvious to one of ordinary skill in the art to have applied the methods of Suddarth et al with the prescription and treatment methods of Kapatoes et al for the purpose of allowing for a broad measure of treatment and assessment methods for analyzing therapies applied to the body.

Response to Arguments

Applicant's arguments filed 5/22/09 have been fully considered but they are not persuasive. Regarding Applicant's first argument that Suddarth always begins with radiation detection, and thus cannot be monitoring factors external to an area of interest, Examiner respectfully disagrees with Applicant's assessment of the current claim language. The current claim language does not preclude one from monitoring radiation so long as some measurement or observation of external factors is performed. This means that monitoring radiation does not preclude Suddarth from performing a general metabolic assessment to read on claim 1. Regarding the arguments levied against claim 31, namely that comparison of a treatment to a reference plan in order to create a modified treatment plan, Examiner respectfully disagrees. Kapatoes discloses "a method for modifying a prepared radiation treatment plan in response to a detected change in a tumor or the like", and therefore discloses a variation or modification capable of calculating a cumulative dose, and subsequently modifying treatment for a future treatment based on this analysis (Col 3 Line 20-Col 4 Line 15).

Regarding Applicant's arguments against the rejections of claims 33 and 34, namely that Kapatoes in view of Suddarth does not disclose a time course treatment plan where a second therapeutic application occurs during a second session, Examiner respectfully disagrees with Applicant's assessment of the term "session". A session can comprise a single radiation treatment and a subsequent session could comprise a second or modified session performed while the patient remains in position but a time has elapsed in order to assess the first treatment.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure includes standard care practices of the NCCN (National Comprehensive Cancer Network www.nccn.org) and other Oncology standards groups which explicitly disclose in their standards of care the monitoring of a patient's well-being, assessment of treatments during a course of treatment which can comprise many sessions of radiation therapy, assessment of adjuvant therapy for treatment of side-effects of treatment either systemically or locally, as well as restaging and recurrence therapy in the event of carcinoma remaining after the therapy has run its course.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/JOEL M LAMPRECHT/

Examiner, Art Unit 3737

/BRIAN CASLER/

Supervisory Patent Examiner, Art Unit 3737